

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Veterinary Antimicrobial Decision Support System**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

*DMB*

Display Date	<u>12-28-00</u>
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Certifier	<u>S. K. R. R.</u>

**SUMMARY:** The Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) announces that funds may be available to support an unsolicited grant application submitted by Iowa State University. The applicant has requested funds to develop a web-based, peer-reviewed antimicrobial decision support system centered on therapeutic applications that will allow food animal veterinary practitioners to utilize all available information in the construction of antimicrobial regimens.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding the administrative and financial management aspects of this notice:* Peggy L. Jones, Division of Contracts and Procurement Management (HFA-520), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301-827-7160. Correspondence hand-carried or commercially delivered should be addressed to 5630 Fishers Lane (HFA-520), rm. 2129, Rockville, MD 20857.

*Regarding the programmatic aspects of this notice:* David B. Batson, Office of Research, Center for Veterinary Medicine (HFV-502), Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708, 301-827-8021.

**SUPPLEMENTARY INFORMATION:**



## **I. Purpose of the Project**

The specific aims of the project are as follows: (1) Perform extensive literature searches to identify pharmacokinetic, pharmacodynamic, clinical trial, antimicrobial pathogen susceptibility, regulatory, food safety, and approval process information pertinent to the veterinary antimicrobial decision support system (VADS); (2) develop and apply standard operating procedures for evaluating the quality and reliability of information and data for use in developing the VADS system contents; (3) apply the principles of pharmacology in constructing therapeutic regimens for use when approved antimicrobial products are not effective as labeled; (4) design a relational database allowing a user to efficiently search the VADS system for label and extralabel regimens based on therapeutic applications, and to then review regulatory and food safety information applicable to these regimens; and (5) subject the VADS system content to review prior to release and then constantly upgrade the content on the basis of new information and review by users.

## **II. Eligible Applicants**

Assistance may only be provided to Iowa State University because of the following:

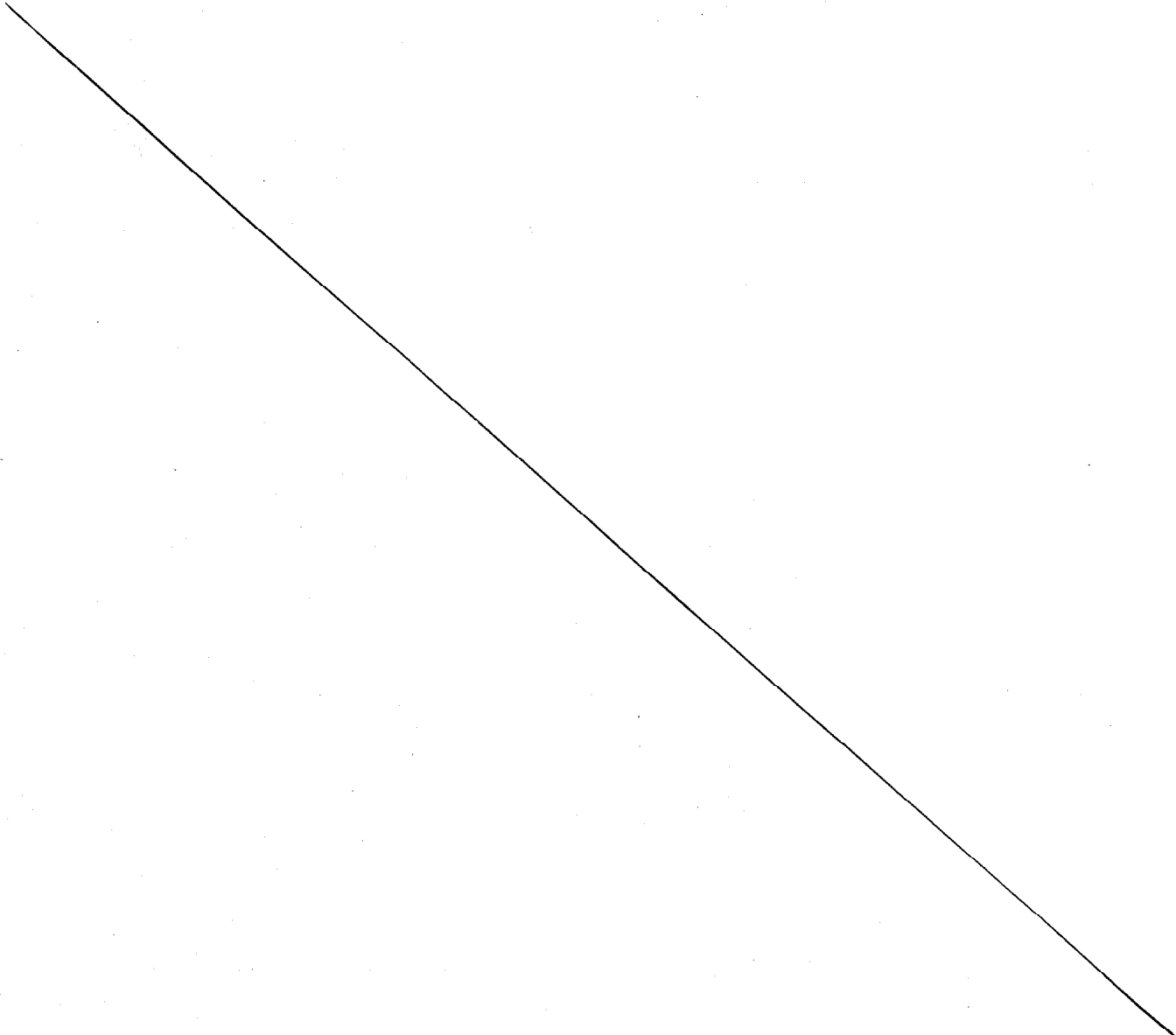
1. Iowa State University is the only organization that submitted an unsolicited application for the purpose stated above.
2. The project proposed by the applicant is unique and innovative in that pharmacokinetic, pharmacodynamic, clinical trial, and pathogen susceptibility information will be interpreted by clinical pharmacologists and reviewed by other experts in the appropriate fields prior to inclusion in the system. Users may either use the information as provided or examine the transparent development process used in constructing the system. In addition, by compiling available information to support prudent antimicrobial use, the VADS system will emphasize what information is not available, thereby aiding researchers in targeting research goals.
3. The team assembled to carry out the proposed work is uniquely qualified to achieve the goals of this application. Their combined experience encompasses practice in academic, general, and specialized production medicine settings as well as demonstrated competence in the application



of clinical pharmacology and informatics in veterinary medicine. Support for the research team and the VADS system project has already been expressed in the form of start up funding provided by veterinary and producer organizations.

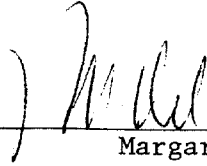
### **III. Funding**

We anticipate that approximately \$250,000 may be made available in fiscal year (FY) 2001 to support this project. If funded the award will begin sometime in FY 2001 and will be made for a 12-month budget period within a project period of up to 5 years. Funding estimates may change. Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.





Dated: 12/22/00  
December 22, 2000.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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